Page 8 of 13

Amendment and Response Serial No.: 10/620,548 Confirmation No.: 8448

Filed: 16 July 2003 For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

#### Remarks

The Office Action mailed 26 September 2005 has been received and reviewed. Claims 1-4 having been amended and claims 5-19 having been added, the pending claims are claims 1-19. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 1, 3, and 4 have been amended to recite a "composition comprising about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier based on the total weight of the composition." The amendment is supported by the specification at, for example, page 2, lines 23-25.

Claims 1, 3, and 4 have further been amended to recite that "the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pre-treatment temperature." The amendment is supported by the specification at, for example, page 2, line 31 to page 3, line 1.

Claim 2 has been amended to correct an obvious typographical error so as to properly depend from claim 1.

New claims 5 and 6 are supported by the specification at, for example, page 2, lines 2-3. New claim 7 is supported by the specification at, for example, page 6, lines 21-22. New claim 8 is supported by the specification at, for example, page 5, lines 14-16. New claim 9 is supported by the specification at, for example, page 7, lines 25-29. New claim 10 is supported by the specification at, for example, page 5, lines 2-3. New claims 11-14 are supported by the specification at, for example, page 8, line 29 to page 9, line 18.

New claims 14, 16, and 18 are supported, for example, by originally filed claims 1, 3, and 4, respectively, and the specification at page 8, line 29 to page 9, line 18. New claims 15, 17, and 19 are supported, for example, by originally filed claims 1, 3, and 4, respectively, and the specification at page 8, line 29 to page 9, line 18.

Page 9 of 13

Amendment and Response Serial No.: 10/620,548 Confirmation No.: 8448

Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

# Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-4 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

First, the Examiner alleged that claims 1-4 are indefinite insofar as the basis for the percent by weight calculation is not set forth. Claims 1, 3, and 4 have been amended to recite a "composition comprising about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier based on the total weight of the composition." Applicants respectfully submit that the claims as amended clearly recite the basis for percent by weight, and thus, that rejection has been obviated.

Next, the Examiner also alleged that the terms "low viscosity" and "highly viscous" in claims 1, 3, and 4 are relative terms, which render the claims indefinite. Applicants respectfully traverse the rejection.

"The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph.... Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." M.P.E.P. §2173.05(b).

Applicants respectfully submit that one of skill in the art would understand what is claimed in light of the specification. Specifically, Applicants submit that one of skill in the art, in light of the specification, would recognize that the terms objected to by the Examiner, i.e., "low viscosity" and "highly viscous," are clearly reflective of an increase in viscosity of the composition in response to an increase in temperature (e.g., page 2, lines 14-15 and 31).

However, in the interest of expediting the prosecution of the present application, claims 1, 3, and 4 have been amended herein to recite that "the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the preAmendment and Response

Scrial No.: 10/620,548 Confirmation No.: 8448 Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

Page 10 of 13

treatment temperature." Thus, Applicants respectfully submit that the rejection has been obviated.

Finally, the Examiner alleged that claim 2 is incomplete insofar as it depends on a nonexistent (canceled) claim. Claim 2 has been amended to correct an obvious typographical error so as to properly depend from claim 1. Thus, Applicants respectfully submit that the rejection has been obviated.

For at least the reasons presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §112, second paragraph.

### Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 1 and 3 under 35 U.S.C. §102(b) as being anticipated by Vacanti (U.S. Patent No. 5,944,754). Claims 1 and 3 have been amended. However, to the extent that the rejection applies to claims 1 and 3 (as amended), Applicants respectfully traverse the rejection.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02 (emphasis added).

Applicants respectfully submit that amended claims 1 and 3 are not anticipated by Vacanti because such document does not teach each and every aspect of the claimed invention. Vacanti lacks, among other things, a disclosure that "the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pretreatment temperature" (e.g., claims 1 and 3, as amended).

As such, Applicants respectfully submit that claims 1 and 3 are not anticipated by Vacanti. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Amendment and Response

Serial No.: 10/620,548 Confirmation No.: 8448 Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

Page 11 of 13

## Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 2 and 4 under 35 U.S.C. §103(a) as being unpatentable over Vacanti (U.S. Patent No. 5,944,754). Claims 2 and 4 have been amended. However, to the extent that the rejection applies to claims 2 and 4 (as amended), Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143.

Applicants respectfully submit that the cited document does not teach or suggest all of the language recited in the present claims. Vacanti lacks, among other things, a disclosure or suggestion that "the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pre-treatment temperature" (e.g., claims 1 and 3, as amended).

As such, Applicants respectfully submit that claims 2 and 4 are not obvious over Vacanti.

The Examiner rejected claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over Oxman et al. (U.S. Patent No. 6,312,666) or Trom et al. (U.S. Patent Nos. 6,669,927 or 6,312,667), each primary reference being considered individually and separately and each being taken in view of Vacanti (U.S. Patent No. 5,944,754). The Examiner also rejected claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over Oxman et al. (U.S. Patent No. 6,312,666) or Trom et al. (U.S. Patent Nos. 6,669,927 or 6,312,667), each primary reference being considered individually and separately and each being taken in view of Hill et al. (U.S. Patent No. 5,032,387). Applicants respectfully traverse these rejections.

Applicants respectfully submit that Oxman et al. (U.S. Patent No. 6,312,666) and Trom et al. (U.S. Patent Nos. 6,669,927 or 6,312,667) are not available as prior art for purposes of obviousness in view of 35 U.S.C. §103(c) as effective November 29, 1999. At the time the invention of the instant application was made, the claimed invention and over Oxman et al. (U.S.

Page 12 of 13

Amendment and Response

Serial No.: 10/620,548 Confirmation No.: 8448 Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

Patent No. 6,312,666) and Trom et al. (U.S. Patent Nos. 6,669,927 or 6,312,667), were owned by or subject to an obligation of assignment to the same entity.

As such, Applicants respectfully submit that the rejection has been rendered moot. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a).

### **New Claims**

New claims 5-13 depend from claim 4. Applicants respectfully submit that claims 5-13 are patentable for at least the same reasons that claim 4 is patentable, in addition to reasons related to the additional subject matter contained therein.

New claims 14, 16, and 18 recite an adjuvant selected from the group consisting of acids, peroxides, fluoride sources, medicaments, stability promotors, acid neutralizers, preservatives, adhesive modifiers, fillers, dyes, flavorings, sweeteners, and breath fresheners. New claims 15, 17, and 19 recite an adjuvant selected from the group consisting of anti-microbial agents, anticalculus agents, anti-fungal agents, cariostatic agents, local anesthetics, glucose oxidases, lactoperoxidases, and sodium bicarbonate. Applicants respectfully submit that claims 14-19 are patentable for reasons similar to the patentability of claims 1-4 and for the additional subject matter contained therein.

Amendment and Response

Serial No.: 10/620,548 Confirmation No.: 8448 Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST

Page 13 of 13

### Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted By Mueting, Raasch & Gebhardt, P.A. P.O. Box 581415 Minneapolis, MN 55458-1415

Phone: (612) 305-1220 Facsimile: (612) 305-1228

Decontes 21,000

Date

Loren D. Albin

Reg. No. 37,763

Direct Dial (612) 305-1225

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2745 day of December, 2005, at 440 practice. (Central Time).

By:

By: Sue Ambrosko Name: Sue Dambrosko